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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 00N-1268]

**Agency Information Collection Activities; Proposed Collection; Comment Request;  
Food Additives and Food Additive Petitions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the approval and labeling of food additives.

**DATES:** Submit written comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Additives and Food Additive Petitions—21 CFR 171.1 and Parts 172, 173, 175 through 178, and 180—(OMB Control Number 0910–0016)—Extension**

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that any particular use or intended use of a food additive shall be deemed to be unsafe, unless the additive and its use or intended use are in conformity with a regulation issued under Section 409 of the act that describes the condition(s) under which the additive may be safely used, or unless the additive and its use or intended use conform to the terms of an exemption for investigational use, or unless a food contact notification submitted under paragraph (h) is

effective. Food additive petitions are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175 through 178, and 180 (21 CFR parts 172, 173, 175 through 178, and 180) contain labeling requirements for certain food additives to ensure their safe use.

FDA scientific personnel review food additive petitions to ensure the safety of the intended use of the food additive in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food. FDA requires food additive petitions to contain the information specified in § 171.1 in order to determine whether a petitioned use for a food additive is safe, as required by the act. This regulation (§ 171.1) implements section 409(b)(2) of the act.

Respondents are businesses engaged in the manufacture or sale of food, food ingredients, or substances used in materials that come into contact with food.

FDA estimates the burden of this collection of information as follows:

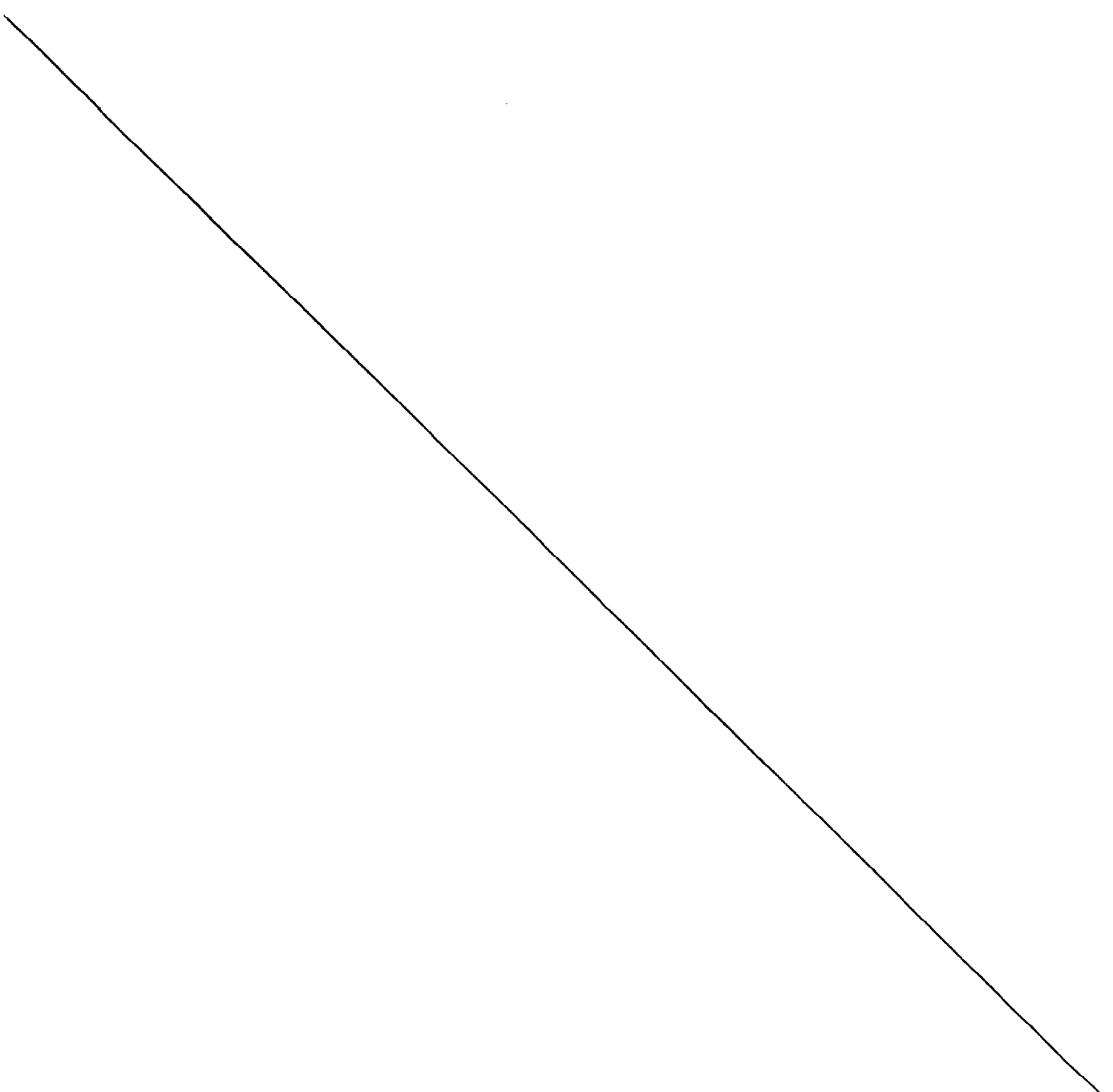
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/Part	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
171.1	13	1	13	5,332	69,316
Part 172	13	1	13	0	0
Part 173	13	1	13	0	0
Parts 175 through 178	13	1	13	0	0
Part 180	13	1	13	0	0
Total					69,316

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on the number of new food additive petitions received in fiscal year 1999 and the total hours expended by petitioners to prepare the petitions. A reduction was estimated based on expected eligibility of some substances previously submitted as food additive petitions for submission as food contact notices under new section 409(h) of the the act. The burden varies with the complexity of the petition submitted, because food additive petitions involve the analysis

of scientific data and information, as well as the work of assembling the petition itself. Because labeling requirements under parts 172, 173, 175 through 178, and 180 for particular food additives




involve information required as part of the food petition safety review process under § 171.1, the estimate for the number of respondents is the same and the burden hours for labeling are included in the estimate for § 171.1.

Dated: May 9, 2000



William K. Hubbard  
Senior Associate Commissioner for  
Policy, Planning, and Legislation

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL  


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